(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 August 2002 (01.08.2002)

PCT

(10) International Publication Number
WO 02/058780 A1

(51) International Patent Classification[7]: A61M 25/095, 25/06 // A61B 17/00, A61N 1/05

(21) International Application Number: PCT/NO02/00013

(22) International Filing Date: 11 January 2002 (11.01.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2001 0184 11 January 2001 (11.01.2001) NO

(71) Applicant *(for all designated States except US)*: **MEDINNOVA SF** [NO/NO]; Rikshospitalet, Signsveien 20, N-0027 Oslo (NO).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **BERNTSEN, Rolf, F.** [NO/NO]; Husebybakken 48, N-0379 Oslo (NO).

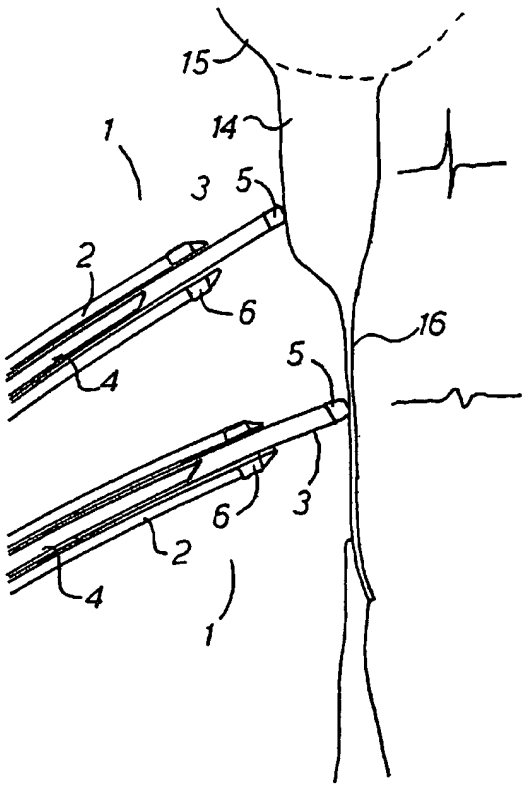
(74) Agent: **PROTECTOR INTELLECTUAL PROPERTY CONSULTANTS AS**; P.O. Box 5074, Majorstuen, N-0301 Oslo (NO).

(81) Designated States *(national)*: AE, AG, AL, AM, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), DE (utility model), DK (utility model), DM, DZ, EC, EE (utility model), ES, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent

[Continued on next page]

(54) Title: DEVICE AND METHOD FOR LOCALIZATION OF FOSSA OVALIS



(57) Abstract: A device to be used for transvenous access to the left atrium by transseptal puncture through fossa ovalis is described. The device comprises a dilator (2) inside an insertion sleeve (1), where the dilator (2) is protruding out of the insertion sleeve. A channel for a puncture needle (4) for puncturing the auricular septum is provided in the dilator. An apical electrode (5) is provided at the tip of the dilator (2) and a reference electrode (6) is provided proximal to the apical electrode. An abrupt drop in the voltage potential between the electrodes (5, 6) confirms the localisation of the apical electrode at fossa ovalis. A method for localisation of fossa ovalis is also described.

WO 02/058780 A1

(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE AND METHOD FOR LOCALIZATION OF FOSSA OVALIS

The present invention relates to the medical field. More precisely, the present invention relates to a device and method for getting access by a catheter to the left atrium via *vena cava inferior*. Specifically, the invention relates to a device and a method for localisation of *fossa ovalis* for a transseptal puncture for getting access to the left atrium.

RF catheter ablation has in the last decade become the preferred choice for the treatment of several arrhythmia conditions of the heart. For arrhythmia's originating from the left atrium such as auricular fibrillation, left atrium tachycardia etc., a safe and uncomplicated access to the left atrium is desirable. Auricular fibrillation here represents the greatest challenge both technically and clinically.

According to the retrograde transaortal technique for getting access for a catheter to the left atrium, a catheter is led via aorta to the left ventricle and from there to the left atrium. This, however, gives a complicated path for the catheter that is long and has two bends, each of hem 180°. This results in strongly reduced manoeuvrability. Therefore, this technique cannot be used for the new advanced diagnostic and therapeutic catheters. Additionally said new catheters are too rigid for this complicated catheter track. Additionally the transaortal technique adds the risk of damaging the corona arteries, aorta valves and the mitral apparatus, in addition to complications as heamatomas, pseudo aneurysm, thrombosis, AV fistula formation, dissection and embolism from either the catheter, aortal walls or from calcified aorta or mitral valves. High risk for complications may alone contraindicate a transaortal procedure. For patients having mechanical aortal or mitral valves the procedure is absolutely contraindicated.

Transseptal puncturation is the alternative in cases where the transaortal procedure is contraindicated or if the goal cannot be reached via aorta. The catheter is then lead upwards via the right femoral vein and up in the right atrium. From here the catheter is led through the fossa ovalis membrane that is the thinnest, membranous part of the atrial septum.

The advantages by this method are that the method is transveinous and that the path of the catheter is simple and relatively straightforward, giving good manoeuvrability and possibility to introduce complex catheters. Additionally most of the above-mentioned serious complications connected to the transaortal technique are avoided. The disadvantages are that the transveinous access to the left atrium demands great vigilance and experience to avoid complications. The most important complication is incorrect puncturation resulting in perforation of the atrium or aorta a complication that may result in life-threatening bleeding complication. It is therefore of vital importance to have a good, simple and reliable method to localise fossa ovalis.

Transveinous access to the left atrium by transseptal puncturation is not a new technique but was used for some purposes as early as the 1950's. The main features in the traditional method for localisation of fossa ovalis for transseptal puncturation are mainly the same as then and are as follows:

An insertion sleeve with a dilatator, commonly denoted as an inserter, is inserted under X-ray control into *vena cava superior* (VCS) after puncturation of a vein using standard Seldinger technique. After pulling out the guide wire and flushing the insertion sleeve, a puncturation needle, as exemplified by a Brockenbrough needle, is inserted into the insertion sleeve and into the dilatator and is stopped about 10 mm from the tip of the dilatator. The dilatator and the puncturation needle constitute the so-called puncturation set. Equipment for measuring the pressure in the sleeve is then connected to the puncturation set. The puncturation set is then turned to the left and somewhat backwards so that the dilatator rests against the wall of VCS. The puncturation set is then pulled slowly downwards against the inlet to the right atrium. A first abrupt movement of the puncturation set to the left verifies that the tip of the puncturation set, the dilatator, has moved from the VCS and into the atrium.

A new movement towards the left occurs when the puncturation set is pulled further down and the tip of the set enters the atrial septum right below the base of aorta. When the puncturation set is pulled further down a further movement towards the left occurs when the tip of the puncturation set rests against the fossa ovalis membrane. The

position and placement of the tip of the puncturation set is then confirmed by means of X-ray in the right oblique projection. After confirming the correct position of the tip of the puncturation set, the puncturation needle is pushed out through the tip of the puncturation set, through the fossa ovalis part of the atrial septum and into the left atrium. The pressure in the insertion sleeve is continuously measured during the puncturation. The expected pressure in the left atrium confirms a correct puncturation. After the puncturation needle is pushed through the atrial septum the dilatator and the insertion sleeve is pushed through the hole made by the needle. Some surgeons additionally utilise echocardiograph to assure that the puncturation set is in the correct position before the puncturation is performed. Other surgeons are injecting a contrast liquid to verify the position of the needle before the dilatator and the insertion sleeve are pushed after the needle.

Erroneous puncturations happen even for experienced surgeons as the movements of the catheter and / or the x-ray may be misinterpreted. The result of such erroneous puncturation may be life-threatening haemorrhages and may in some instances require a surgery. This risk and the demand for substantial experience has resulted in that the threshold to start using the transseptal technique is high.

Accordingly, there is a need for a method and a device making it possible in a more secure and reliable way to identify the fossa ovalis membrane so that transseptal puncturation may be executed with higher security and thus lower the threshold against using this technique.

According to a first aspect a device for transvenous access to the left atrium by transseptal puncturation is provided, where the device comprises a dilator placed inside an insertion sleeve, the dilatator protruding from the insertion sleeve and where the dilatator is provided with a channel for a suitable puncturation needle for puncturation of the atrial septum, wherein a apical electrode is provided at the tip of the dilatator and a proximal reference electrode is provided at a distance from the apical electrode so that a abrupt drop in the voltage potential between the apical and proximal electrodes confirms that the apical electrode rests against fossa ovalis.

Preferably the apical electrode is a ring electrode placed around the channel in the dilator.

The distance between the reference electrode and the apical electrode is preferably 5 to 30 mm, more preferably 10 to 15 mm.

According to a preferred embodiment the puncturation needle is used as reference electrode.

According to a second aspect of the present invention there is provided a method for localisation of the *fossa ovalis* membrane, wherein a catheter having a apical electrode at its apical tip and a reference electrode at a distance proximal to the apical electrode, where the apical tip and the apical electrode resting against and being moved against the atrial septum, where the voltage potential between the apical and proximal electrodes is registered, and where it is confirmed by an abrupt drop in the voltage potential that the apical electrode rests against *fossa ovalis*..

Preferably the fall in the voltage potential for confirming that the apical electrode rests at the fossa ovalis membrane, is a drop from approx. 2.5 – 3.5 mV to less than 0.5 mV.

Preferably the method is used for localisation of *fossa ovalis* before puncturation of *fossa ovalis* for transvenous access to the left atrium.

The invention will in the following be described in further detail with reference to the attached figures, wherein

Fig. 1 is a schematic view of the track of the catheter by respectively the transaortal and transseptal access to the left atrium,

fig. 2 is a schematic cross-section of *vena cava superior*, the left atrium and the atrial septum and illustrates the traditional method for identification and puncturation of fossa ovalis, and

fig. 3 is a cross-section of a dilatator and a insertion sleeve according to the present invention and through the atrial septum and *fossa ovalis*.

It is evident from fig. 1 that the track of the catheter by the transaortal (I) access (dotted line) to the left atrium is very complicated. Actually it is so complicated that it is not applicable to modern, advanced catheters. The transseptal access gives a much shorter, simpler and almost straight track of the catheter (solid line).

Fig. 2 illustrates in steps the traditional method for localisation of fossa ovalis. An inserter, comprising a insertion sleeve 2 and a dilatator 3 is inserted via *vena cava inferior* 10 into vena *cava superior* 11. A Brockenbroughnål 4 is inserted into the dilatator 3 ending approx. 10 mm from the tip of the dilatator 3. The dilatator 3 and the puncturation needle 4 are jointly referred to as a puncturation set. The dilatator protruding form the insertion sleeve 2 is now resting against the wall of *vena cava superior*. The puncturation set is then pulled downwards as described above. The first movement towards the left corresponds to the tip of the dilator moving from VCS 11 and into the right atrium 12 (see arrow A). By further downwards pulling of the puncturation set the tip of the dilatator again moves towards left when the tip is entering the atrial septum below the base of aorta (see arrow B). A further movement of the puncturation set to the left when it is pulled further down, indicates that the tip of the dilatator enters the fossa ovalis membrane (arrow C). The Brockenbrough needle 4 is then pushed through to puncture the fossa ovalis membrane and the dilator 3 and the insertion sleeve is pushed after the needle through the same hole into the left atrium 17.

The present invention is based on the fact that distinct differences in the signal amplitude, i.e. differences in voltage potential are present in the bipolar electrogram between the muscular and membranous part of the atrial septum, wherein fossa ovalis comprises the membranous part.

The inserter 1 according to the present invention as illustrated in fig. 3, is based on a traditional inserter 1 comprising an insertion sleeve 2 within which a dilatator 3 and a puncturation needle 4, such as a Brockenbrough needle, are provided. Both the insertion

sleeve and the dilatator 3 are tubes made of synthetic material having a suitable rigidity adapted to the purpose. An apical electrode 5, preferably a ring electrode, is placed at the tip of the dilatator 3 around the opening thereof. A reference electrode 6 is placed 5 to 30 mm, preferably 10 to 15 mm, more proximal at the inserter 1. The apical electrode 5 and the proximal electrode 6, optionally another ring electrode, are both connected to external measuring equipment by means of conductors traditionally used in catheters.

When the apical electrode 5 rests against the muscular part of the atrial septum and by using traditional measuring equipment for the purpose, a distinct bipolar electrogram may be registered due to local voltage differences between the apical 5 and the proximal 6 electrodes. The amplitudes of said distinct local electrogram from the muscular part of the atrial septum is normally in the magnitude of 1.5 to 3.5 mV. When the apical electrode has passed *limbus* and enters the membranous *fossa ovalis,* the amplitude of the signal has an abrupt drop to below 0.5 mV.

This abrupt and distinct drop in amplitude confirms that the apical electrode 5, and thus the tip of the dilatator 3, rests against the *fossa ovalis* membrane. This gives the surgeon an indication and confidence for the correct localisation of the site for puncturation. When the correct localisation has been confirmed the punctuation needle 4 is pushed through the opening of the dilatator and through the fossa ovalis membrane to puncture the membrane.

The correct position of the punctuation needle may also be confirmed after it is pushed through the membrane by means of pressure measurements and/or x-ray. After the optional confirmation of correct position of he needle, the dilatator and thereafter the insertion sleeve is pushed through the hole made by the puncturation needle. After pushing the insertion sleeve through the hole in fossa ovalis, the puncturation needle and the dilatator is pulled out of the insertion sleeve and replaced by the catheter to be used for the planned procedure in the left atrium.

Patent claims

1.

Device for transvenous access to the left atrium by transseptal puncturation, where the device comprises a dilator (2) placed inside an insertion sleeve (1), the dilatator (2) protruding from the insertion sleeve and where the dilatator (2) is provided with a channel for a suitable puncturation needle (4) for puncturation of the atrial septum, wherein a apical electrode (5) is provided at the tip of the dilatator (2) and a proximal reference electrode (6) is provided at a distance from the apical electrode (5) so that a abrupt drop in the voltage potential between the apical and proximal electrodes confirms that the apical electrode rests against fossa ovalis.

2.

Device according to claim 1, wherein the apical electrode (5) is a ring electrode placed around the channel in the dilator (2).

3.

Device according to claim 1 or 2, wherein the distance between the reference electrode and the apical electrode is 5 to 30 mm, preferably 10 to 15 mm.

4.

Device according to claim 1 or 2, wherein the puncturation needle (4) is used as reference electrode (2).

5.

Method for localisation of the *fossa ovalis* membrane, wherein a catheter having a apical electrode (5) at its apical tip and a reference electrode (6) at a distance proximal to the apical electrode, where the apical tip and the apical electrode (5) resting against and are moved against the atrial septum, where the voltage potential between the apical (5) and proximal (6) electrodes is registered, and where it is confirmed by an abrupt drop in the voltage potential that the apical electrode rests against *fossa ovalis*..

6.

Method according to claim 5, wherein the fall in the voltage potential for confirming that the apical electrode rests at the fossa ovalis membrane, is a drop from approx. 2.5 – 3.5 mV to less than 0.5 mV.

7.

Method according to clam 5 or 6, wherein the method is used for localisation of *fossa ovalis* before puncturation of *fossa ovalis* for transvenous access to the left atrium.

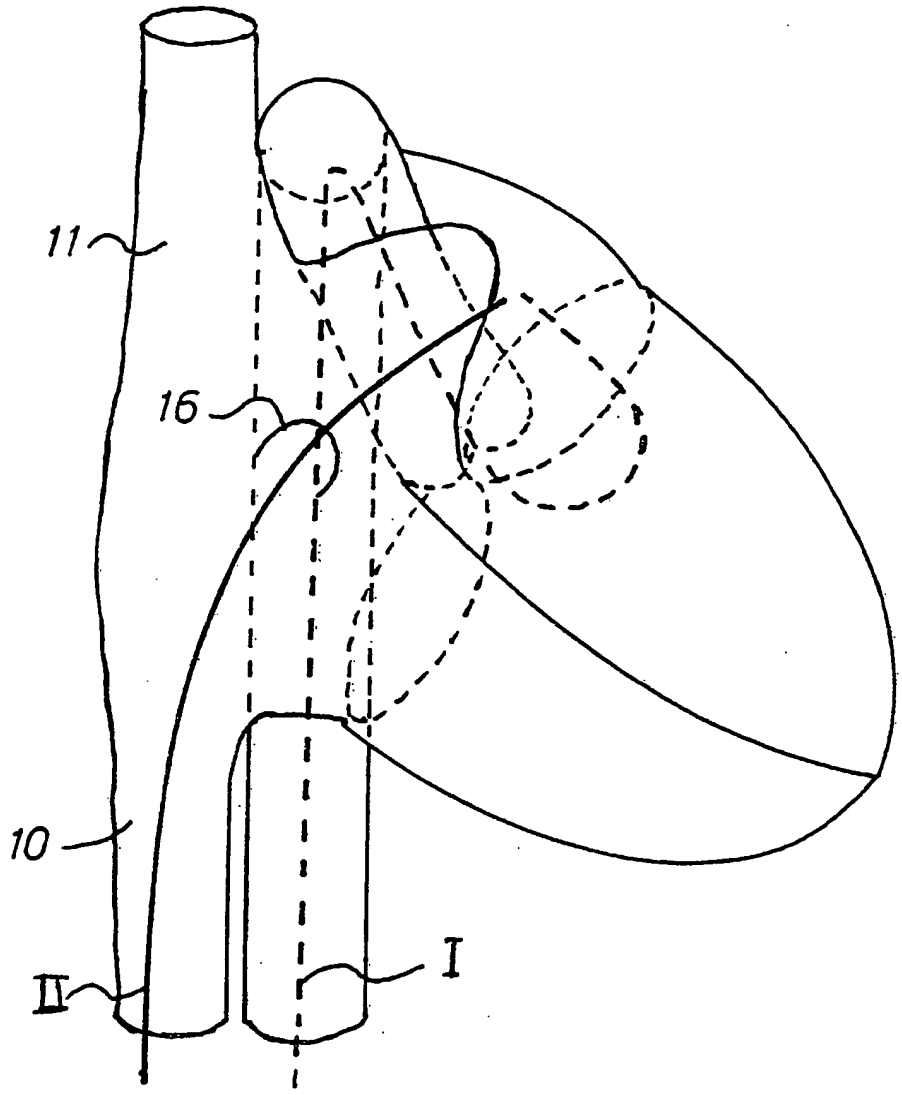


FIG.1

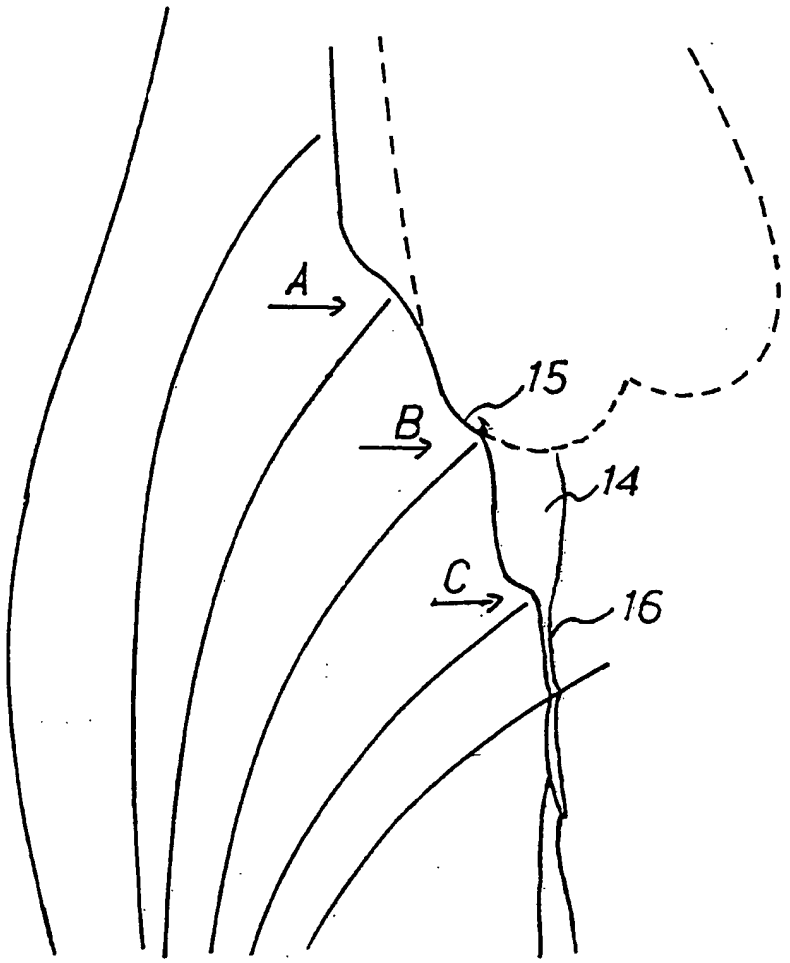


FIG.2

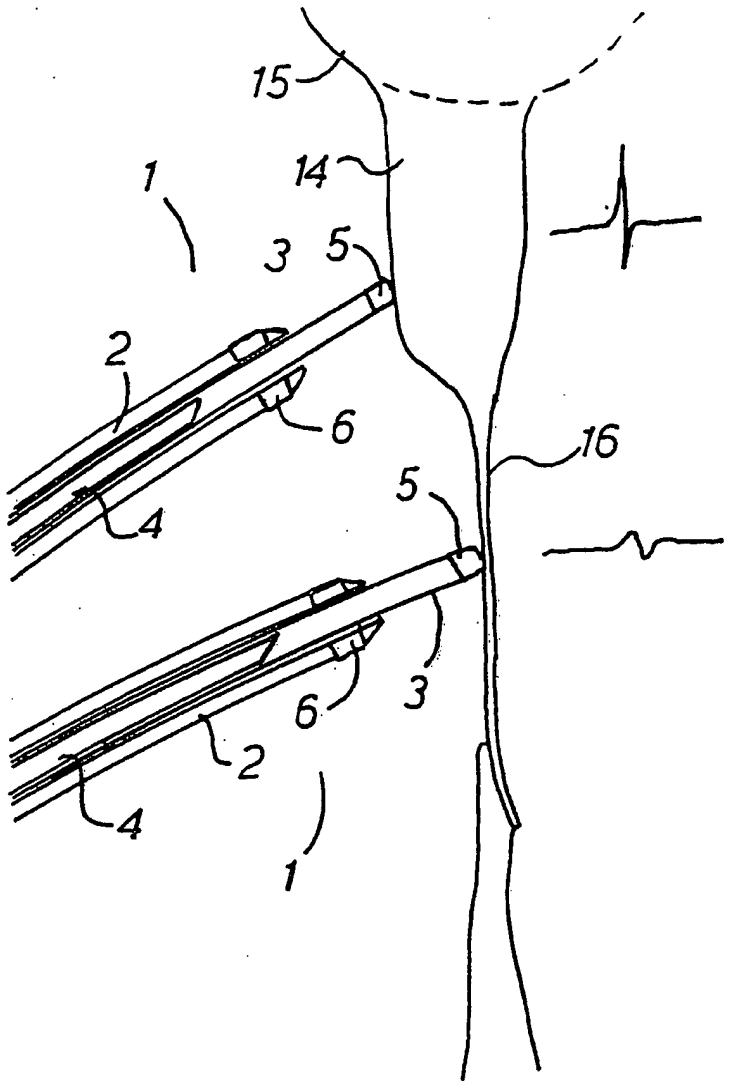


FIG.3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 02/00013

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 25/095, A61M 25/06 // A 61 B 17/00, A 61 N 1/05
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	WO 0178596 A1 (APRIVA MEDICAL, INC.), 25 October 2001 (25.10.01), page 2, line 23 - page 3, line 13, figures 1,8	1-7
A	SU 1480813 A1 (MOSCOW MEDICAL INSTITUTE), 23 May 1989 (23.05.89), abstract	1-7
P,A	US 6200315 B1 (J.W. GAISER ET AL.), 13 March 2001 (13.03.01), column 2, line 30 - line 45, figure 4	1-7
A	US 5984909 A (K.G. LURIE ET AL.), 16 November 1999 (16.11.99), figure 4, abstract	1-7

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 April 2002	06 -05- 2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk/AE Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/01/02

International application No.
PCT/NO 02/00013

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0178596 A1	25/10/01	AU 4547601 A	30/10/01
SU 1480813 A1	23/05/89	NONE	
US 6200315 B1	13/03/01	AU 1727399 A	05/07/99
		US 6241728 B	05/06/01
		WO 9930625 A	24/06/99
US 5984909 A	16/11/99	US 5423772 A	13/06/95
		US 5549581 A	27/08/96
		US 5643231 A	01/07/97
		US 5722963 A	03/03/98
		US 6001085 A	14/12/99
		US 6277107 B	21/08/01